

### REMARKS

The Applicants' would like to thank the Examiners Simpson and Severson for the interview extended to Applicants' representatives. As set forth in the interview, the Final Office Action dated February 19, 2009 has been received and reviewed. By way of summary, Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-90 were previously pending in the above-identified application. Applicants have amended Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89. Claims 29, 51, 64, 76 and 90 have been canceled without prejudice or disclaimer. Accordingly, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 are presented for further consideration.

**A. Response to Rejections of Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86**

The Office Action rejected Claims 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pub. No. 2002/0099431 by Armstrong et al. ("Armstrong"). In the alternative, the Office Action rejected 25, 27-29, 47, 49-51, 60, 62-64, 72, 74-76 and 83-86 under 35 U.S.C. § 103(a) as being obvious over Armstrong in view of U.S. Pat. No. 5,776,141 to Klein et al. ("Klein"). Applicants respectfully disagree with these rejections. However, Applicants have amended Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-86 to clarify certain claimed features, as discussed in the interview. In particular, neither Armstrong nor Klein disclose, teach or suggest establishing a lumen from outside the skin into the renal collection system. Applicants have canceled Claims 29, 51, 64 and 76 without prejudice or disclaimer. Applicants reserve the right to pursue any of the previously presented or canceled claims in one or more related applications.

**1. Independent Claim 25**

As amended, Claim 25 recites, and Armstrong, either alone or in combination with Klein, fails to disclose, *inter alia*, "a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile" and "removing said balloon from the interior lumen of said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end." Neither Armstrong nor Klein teach the recited "tapered region." Furthermore, Armstrong is directed to the

“deployment of...implantable *intraluminal* devices” and Klein is directed to the “delivery of *intravascular* stents,” neither of which provide a “lumen open to an external environment outside the skin.” Armstrong Spec. ¶ 0002 (emphasis added); Klein Spec., col. 1, ln. 17 (emphasis added). Accordingly, Applicants respectfully request that the rejection of Claim 25 be withdrawn and that Claim 25 be passed to allowance.

**2. Independent Claim 47**

As amended, Claim 47 recites, and Armstrong, either alone or in combination with Klein, fails to disclose, *inter alia*, “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and a beveled distal tip, the proximal region having a second, greater cross-sectional profile” and “removing said balloon from the interior region of said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system through said beveled distal tip.” Accordingly, Applicants respectfully request that the rejection of Claim 47 be withdrawn and that Claim 47 be passed to allowance.

**3. Independent Claim 60**

Amended, Claim 60 recites, and Armstrong, either alone or in combination with Klein, fails to disclose, *inter alia*, “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, unfolded, greater cross-sectional profile” and “removing said balloon from said distal region of said elongate tubular structure to open a lumen in said elongate tubular structure, the lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end.” Accordingly, Applicants respectfully request that the rejection of Claim 60 be withdrawn and that Claim 60 be passed to allowance.

**4. Independent Claim 72**

Claim 72 recites, and Armstrong, either alone or in combination with Klein, fails to disclose, *inter alia*, “a tapered region between the distal region and the proximal region, the distal region having a first, smaller cross-sectional profile and a beveled distal tip, the proximal region having a second, greater cross-sectional profile” and “removing said balloon from said distal region of said elongate tubular structure to open a lumen in said elongate tubular structure, the

lumen open to an external environment outside the skin on its proximal end and open to the renal collection system through said beveled distal tip.” Accordingly, Applicants respectfully request that the rejection of Claim 72 be withdrawn and that Claim 72 be passed to allowance.

**5. Dependent Claims 27, 28, 49, 50, 62, 63, 74, 75 and 83-86**

Claims 27, 28, 49, 50, 62, 63, 74, 75 and 83-86 depend directly from one of independent Claims 25, 47, 60 and 72. They are each believed to be patentably distinguished, *inter alia*, for the reasons set forth above in relation to the independent claim from which they depend and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejections of Claims 27, 28, 49, 50, 62, 63, 74, 75 and 83-86 be withdrawn and that these claims be passed to allowance.

**B. Response to Rejections of Claims 87-90 under 35 U.S.C. § 103(a)**

The Office Action rejected Claims 87-90 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 4,738,666 to Fuqua (“Fuqua”) in view of Klein and U.S. Pub. No. 2001/0012950 by Nishtala et al. (“Nishtala”). Applicants have amended Claims 87-89 to clarify the claimed features. Applicants have canceled Claim 90 without prejudice or disclaimer. Applicants reserve the right to pursue any of the previously presented or canceled claims in one or more related applications.

**1. Independent Claim 87**

Claim 87 recites, and Fuqua, either alone or in combination with Klein and Nishtala, fails to disclose, *inter alia*, “a tapered region between the distal region and the proximal region, the distal region having a first, folded, substantially continuous, small cross-sectional profile, the proximal region having a second, unfolded, greater cross-sectional profile” and “removing said balloon from the interior lumen of said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end.”

As discussed in the interview on April 28, 2009, Fuqua is directed to a catheter which “expand[s] to full size as a result of the memory of the system.” Fuqua Spec., col. 5, lines 24-25. Therefore, a person having ordinary skill in the art at the time of invention would not have been motivated to combine the catheter of Fuqua with a balloon such that “inflating a balloon

positioned within said distal region of said elongate tubular structure [] expand[s] and unfold[s] said distal region of said elongate tubular structure from said first, folded, substantially continuous, smaller cross-sectional profile to said second, unfolded, greater cross-sectional profile.”

In addition, as discussed during the interview, it would not be obvious to position a balloon within the interior lumen of the plastic tube 14. As noted above, Applicants believe that it would not be obvious to add a balloon to the device of Fuqua. However, even assuming *arguendo*, that a balloon was added to the device of Fuqua it would not be obvious to place the balloon within the interior lumen of the tube 14. As noted in the interview, at best, one of skill in the art would place the balloon within the fold 15 (see illustrations from Fuqua below) and not within the interior lumen of the tube 14.

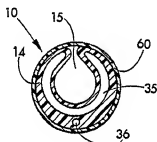


FIG. 1

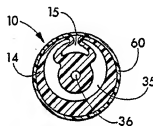


FIG. 3

## 2. Dependent Claims 88 and 89

Claims 88 and 89 depend directly from Claim 87. They are each believed to be patentably distinguished, *inter alia*, for the reasons set forth above in relation to Claim 87 and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejections of Claims 88 and 89 be withdrawn and that these claims be passed to allowance.

## C. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other

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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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